



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,454	11/01/2001	Laura McCulloch	JBP-527	4007

27777 7590 03/21/2005

PHILIP S. JOHNSON  
JOHNSON & JOHNSON  
ONE JOHNSON & JOHNSON PLAZA  
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

CELSA, BENNETT M

ART UNIT PAPER NUMBER

1639

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/035,454

Applicant(s)

MCCULLOCH ET AL.

Examiner

Bennett Celsa

Art Unit

1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6, 8-17, 19-27, 29-38, 42-51 and 53-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 51 is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-17, 19-27, 29-38, 42-50 and 53-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/3/04 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. **NOTE:** the present application is being handled by Primary Examiner Bennett Celsa Art Unit 1639 (see correspondence information below).

### ***Status of the Claims***

Claims 1-6, 8-17, 19-27, 29-38, 42-51 and 53-55.

### ***Allowable Subject Matter***

4. Claim 51 is allowable over the prior art of record.
5. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to *explicitly teach* the a topical cosmetic suspension comprising 2% montmorillonite clay and 0.2% tetrasodium pyrophosphate and applicant's argument regarding nonobviousness e.g. the unexpectedly superior (greater than 2x) increase in reducing enzyme activity in the presence of urine was found persuasive with regard to this claim only.

6. The showing of unexpected results is not sufficient to render the remaining claims allowable since:

a. the remaining claims are broader in scope thereby rendering the unexpected result showing noncommensurate and/or;

b. the remaining claims are subject to both new and outstanding anticipation and obviousness rejections.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1639

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

***Outstanding Objection(s) and/or Rejection (s)***

Claims 1-6, 8-17, 19-27, 29-38, 42-50 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minerath, 111 et al. (US 6551607 B1 ) in combination with Hartung et al. (US 5436007).

Minerath teaches methods and compositions for sequestering skin irritants comprising a substrate containing a sequestering agent with an affinity for skin irritants (Coé. 3, lines 55-66). The skin irritants are present in nasal secretion, bodily waste or the external environment (Cod. 6, lines 45-47). The material suitable for the substrate for the composition includes woven and non-woven webs, fabric, scrims, synthetic fibers and natural fibers (Col. 9, line 14 - Col. 10, line 44). The substrate can contain both hydrophobic and hydrophilic sequestering agents (Col. 6, lines 47- 54). The hydrophilic sequestering agents are chosen from clays, talc, diatomaceous earth, silica, calcium

Art Unit: 1639

sulfate and the like (Col. 7, lines 24-58., Col. 16, lines 9-40). The hydrophobic sequestering agents are chosen from modifications of the native sequestrants (Col. 7, line 59 - Col. 8, line 14,\* Col. 16, lines 9-40). The compositions taught can also include lipophilic sequestering agents, humectants, emulsifying surfactants and viscosity enhancers as well as buffering agents, additional active agents, fragrances, dyes, sunscreens, deodorants and combinations thereof (Col. 10, line 54 - Col. 13, line 44). Minerath does not expressly teach what the exact additional components, such as buffering agents or fragrances, can be in the composition.

Hartung teaches a skin composition that can be delivered to the skin via a wipe or diaper (to treat/prevent diaper rash) that comprises sodium citrate as a buffering agent (Col. 3, lines 45-59).

Hartung also teaches that EDTA can be present in the compositions as a viscosity enhancer (Col. 5, lines 29-62). The wipes or diapers of the reference are used to treat diaper rash, which is caused by bodily waste (Col. 6, lines 28-34). EDTA is one member of the Markush group that defines the peptizing agent.

Neither reference teaches the exact concentration ranges or ratios for components of the composition.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate EDTA into a skin care composition as a viscosity enhancer.

With respect to the claimed concentration ranges, absent a clear showing of

Art Unit: 1639

criticality, the determination of particular concentrations is within the skill of the ordinary worker as part of the process of normal optimization.

One of ordinary skill in the art would have been motivated to do this to prepare a topical composition wherein the viscosity of the composition is suitable for topical composition to provide the most suitable delivery of the composition to the skin.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

***New Objection (s) and/or Rejection (s)***

10. Claims 1-4, 9-15, 20-25, 29-38, 48-50 and 53-55 are rejected under 35 U.S.C. 102(a, b, e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Enjolras et al. U.S. Pat. No. 5,091,193 (2/92)

The presently claimed invention is drawn to:

A topical (e.g. solid, see claims 1 and 12) cosmetic composition comprising:

a. a swellable clay (Eg. Talc or hectorite) or adduct thereof;and

b. a peptizing agent (E.g. EDTA)

-These compositions include emulsions which further comprise oil in water (claim 22)

-These composition can be incorporated into articles (e.g. diapers/wipes see claims 42-47) .

-Topical application methods for treating/reducing or preventing enzymatic dermatitis or diaper rash and reducing dermal enzymatic activity by applying these compositions are also claimed (e.g. see claims 36-38, 48-50 and 53-55).

Enjolras et al. Teaches topical (emulsion, creams, gels etc. : including oils see col. 3, lines 1-30) for preventing/treating diaper rash using compositions comprising :

- a. zinc oxide; and
- b. at least one anti-enzyme sufficient to prevent/treat diaper rash.
- c. an inert pharmaceutical carrier

See col. 1, especially lines 55-62.

The patent claims and Examples select chelator phytic acid as a required anti-enzyme.

Examples 1 and 2 BOTH disclose compositions comprising:

Talc and/or hectorite (e.g swellable clays) and the chelator phytic acid.

However, the reference teaches the use of only six (6) chelators one of which includes ethylene diamine tetraacetic acid (EDTA) which is a peptidizing agent within the scope of the presently claimed invention . The selection of EDTA as a substitute for phytic acid from among six (6) chelators makes the EDTA selection immediately envisaged (e.g. anticipated) or alternatively prima facie obvious to one of ordinary skill in the art. See *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); See also MPEP § § 701; 2131.02 and 2144.08. It is noted that the reference individual and ratio amounts of clay and peptidizing agents are within the scope of the presently claimed invention (e.g. peptidizing agent 0-5% ; 10:1 and 1:10). See reference claims; examples. It is noted that to the extent that the reference fails to specifically teach specific ingredient (e.g. emulsifier/oil) amounts optimization of amounts are within the skill of one of ordinary skill in the art; and differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such



Art Unit: 1639

concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

11. Claims 1-4, 9-15, 20-25, 29-38, 42-50 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Enjolras et al. U.S. Pat. No. 5,091,193 (2/92) and Roe et al. WO 99/45973 (9/99).

Enjolras et al. Teaches topical (emulsion, creams, gels etc. : including oils see col. 3, lines 1-30) for preventing/treating diaper rash using compositions comprising :

- a. zinc oxide; and
- b. at least one anti-enzyme sufficient to prevent/treat diaper rash.
- c. an inert pharmaceutical carrier

See col. 1, especially lines 55-62.

The patent claims and Examples select chelator phytic acid as a required anti-enzyme.

Examples 1 and 2 BOTH disclose compositions comprising:

Talc and/or hectorite (e.g swellable clays) and the chelator phytic acid.

However, the reference teaches the use of only six (6) chelators one of which includes ethylene diamine tetraacetic acid (EDTA) which is a peptidizing agent within the scope of the presently claimed invention . The selection of EDTA as a substitute for phytic acid from among six (6) chelators makes the EDTA selection immediately envisaged (e.g. anticipated) or alternatively prima facie obvious to one of ordinary skill in the art. See *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); See also MPEP § § 701;

2131.02 and 2144.08. It is noted that the reference individual and ratio amounts of clay and peptidizing agents are within the scope of the presently claimed invention (e.g. peptidizing agent 0-5% ; 10:1 and 1:10). See reference claims; examples. It is noted that to the extent that the reference fails to specifically teach specific ingredient (e.g. emulsifier/oil) amounts optimization of amounts are within the skill of one of ordinary skill in the art; and differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

The Enjolras reference teaching differs from the presently claimed invention by failing to incorporate their compositions into articles (e.g. diapers). See present claims 42-47.

However, Roe et al. teach incorporating compositions comprising enzyme inhibitors, including the Enjolras reference compositions, into articles including diapers. E.g. See Roe et al., bottom of page 3-top of page 4;

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the Injolras reference compositions into articles as explicitly suggested by the Roe et al. reference

12. Claims 12-16, 19-26, 29-35 and 42-44 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated by Suginaka et al. WO 99/56703 (11/99).

The presently claimed invention is drawn to:

A topical (e.g. suspension: w/o emulsion, solid) cosmetic composition comprising:

- a. a swellable clay (Eg. Talc or hectorite) or adduct thereof;and
- b. a peptizing agent (E.g. EDTA)

-These compositions include emulsions which further comprise oil in water (claim 22)

Suginaka et. al. Teach : topical (e.g. suspension/emulsion) composition comprising:

- a. one or more swellable clays (e.g. see pages 5-6; example):
- b. one or more peptizing agents (e.g. a "peptizer": see pages 6-7 and Example including LAPONITE XLS/XLG) and
- c. an electrolyte (e.g. sodium carbonate which is a "peptizing agent" : see page 4, especially lines 22-30) and
- d. preservative/pH adjustor (e.g. EDTA: which is a "peptizing agene": see bottom of page 4-top of page 5.

It is noted that the reference individual and ratio amounts of clay and peptidizing agents are within the scope of the presently claimed invention (e.g. peptidizing agent 0-5% ; 10:1 and 1:10). See reference claims; examples; see also abstract ,claims and relevant disclosure pages referred to above.

Art Unit: 1639

13. Claims 1-5, 8-16, 19-26, 29-35 and 42-44 are rejected under 35

U.S.C. 102(a,b,e) as being anticipated by Barnett et al. US Pat. No. 4,148,875 (3/79).

The presently claimed invention is drawn to:

A topical (e.g. suspension: w/o emulsion, solid) cosmetic composition comprising:

a. a swellable clay (Eg. Talc or hectorite) or adduct thereof;and

b. a peptizing agent (E.g. EDTA)

Barnett et al. Disclose topical (e.g. emulsion/suspension with solid: see e.g. col. 3-4) composition (e.g. skin toner) comprising:

a. a swellable clay (e.g. smectite/hectorite clay i.e. LAPONITE and BARASYM);

b. a peptizing agent (e.g. bottom of col. 2-top of col. 3). See also example and patent claims. It is noted that the reference individual and ratio amounts of clay and peptidizing agents are within the scope of the presently claimed invention (e.g. peptidizing agent 0-5% ; 10:1 and 1:10). See reference claims; examples; see also abstract ,claims and relevant disclosure pages referred to above

14. Claims 1-6, 8-17, 19-27, 29-38, 42-51 and 53-55 are rejected under 35 U.S.C.

103(a) as being unpatentable over Suginaka et al. WO 99/56703 (11/99) and Schulz WO 97/38735 (10/97). .

The presently claimed invention is drawn to:

A topical (e.g. suspension: w/o emulsion, solid) cosmetic composition comprising:

Art Unit: 1639

a. a swellable clay (Eg. Talc or hectorite) or adduct thereof;and

b. a peptizing agent (E.g. EDTA)

-These compositions include emulsions which further comprise oil in water (claim 22)

-These composition can be incorporated into articles (e.g. diapers/wipes see claims 42-47) .

-Topical application methods for treating/reducing or preventing enzymatic dermatitis or diaper rash and reducing dermal enzymatic activity by applying these compositions are also claimed (e.g. see claims 36-38, 48-50 and 53-55.

Suginaka et. al. Teach : topical (e.g. suspension/emulsion) composition comprising:

a. one or more swellable clays (e.g. see pages 5-6; example):

b. one or more peptizing agents (e.g. a "peptizer": see pages 6-7 and Example including LAPONITE XLS/XLG) and

c. an electrolyte (e.g. sodium carbonate which is a "peptizing agent" : see page 4, especially lines 22-30) and

d. preservative/pH adjustor (e.g. EDTA: which is a "peptizing agene": see bottom of page 4-top of page 5.

It is noted that the reference individual and ratio amounts of clay and peptidizing agents are within the scope of the presently claimed invention (e.g. peptidizing agent 0-5% ; 10:1 and 1:10). See reference claims; examples; see also abstract ,claims and relevant disclosure pages referred to above.

The Suginaka et. al reference differs from the presently claimed invention by failing to:

- a. incorporate clay adducts (e.g. quaternary ammonium: e.g. see claim 6);  
and/or
- b. utilizing the Suginaka composition to prevent diaper rash/treat enzymatic dermatitis or formulation pharmaceutical topics (e.g. solid) for use in absorptive articles e.g. diapers/tampons.

However, Schulz teaches that compositions comprising clays (e.g. quaternary ammonium) can be used to prevent/treat diaper rash by reducing enzymatic dermatitis in topical delivery formulations (e.g. solids etc) and incorporated into diapers.

In this regard, it is noted that Suginaka teaches that its compositions are useful to treat damaged and hyperpigmented skin both conditions present in diaper rash.

Accordingly, one of ordinary skill in the art would have been motivated to incorporate Schultz's clay adducts into the Suginaka compositions instead of the Suginaka clays for the benefits imparted thereon in the use in treating diaper rash and enzymatic dermatitis as emulsions or as other topical delivery formulations (e.g. solid) for treating skin irritation and enzymatic dermatitis.

Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to formulate Suginaka reference compositions to incorporate clay adducts and/or to utilize the Suginaka reference compositions in topical formulations (diapers/tampons) to treat/prevent diaper rash and/or enzymatic dermatitis.

It is noted that to the extent that the references fail to teach specific ingredient (e.g. emulsifier/oil) amounts, optimization of amounts are within the skill of one of ordinary skill in the art; and differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

15. Claims 1-6, 8-17, 19-27, 29-38, 42-51 and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barnett et al. US Pat. No. 4,148,875 (3/79) and Schulz WO 97/38735 (10/97).

The presently claimed invention is drawn to:

A topical (e.g. suspension: w/o emulsion, solid) cosmetic composition comprising:

- a. a swellable clay (Eg. Talc or hectorite) or adduct thereof;and
- b. a peptizing agent (E.g. EDTA)

-These compositions include emulsions which further comprise oil in water (claim 22)

-These composition can be incorporated into articles (e.g. diapers/wipes see claims 42-47) .

-Topical application methods for treating/reducing or preventing enzymatic dermatitis or diaper rash and reducing dermal enzymatic activity by applying these compositions are also claimed (e.g. see claims 36-38, 48-50 and 53-55.

Barnett et al. Disclose topical (e.g. emulsion/suspension with solid: see e.g. col. 3-4) composition (e.g. skin toner) comprising:

- a. a swellable clay (e.g. smectite/hectorite clay i.e. LAPONITE and BARASYM);
- b. a peptizing agent (e.g. bottom of col. 2-top of col. 3). See also example and patent claims. It is noted that the reference individual and ratio amounts of clay and peptidizing agents are within the scope of the presently claimed invention (e.g. peptidizing agent 0-5% ; 10:1 and 1:10). See reference claims; examples; see also abstract ,claims and relevant disclosure pages referred to above

The Barnett reference differs from the presently claimed invention by failing to:

- a. incorporate clay adducts (e.g. quarternary ammonium: e.g. see claim 6);
- and/or
- b. utilizing the Barnett composition to prevent diaper rash/treat enzymatic dermatitis or formulation pharmaceutical topics (e.g. solid) for use in absorptive articles e.g. diapers/tampons.

However, Schulz teaches that compositions comprising clays (e.g. quaternary ammonium) can be used to prevent/treat diaper rash by reducing enzymatic dermatitis in topical delivery formulations (e.g. solids etc) and incorporated into diapers.

In this regard, it is noted that Barnett teaches that its compositions are useful as skin toning cosmetic composition to e.g. to treat damaged skin which would be amenable to address dermatitis conditions including diaper rash.

Accordingly, one of ordinary skill in the art would have been motivated to incorporate Schultz's clay adducts into Barnett compositions instead of the Barnett



clays for the benefits imparted thereon in the use in treating diaper rash and enzymatic dermatitis as emulsions or as other topical delivery formulations (e.g. solid) for treating skin irritation and enzymatic dermatitis.

Thus, it would have been obvious to one of ordinary skill in the art at the time of applicant's invention to formulate Barnett's reference compositions to incorporate clay adducts and/or to utilize the Barnett's reference compositions in topical formulations (diapers/tampons) to treat/prevent diaper rash and/or enzymatic dermatitis.

It is noted that to the extent that the references fail to teach specific ingredient (e.g. emulsifier/oil) amounts, optimization of amounts are within the skill of one of ordinary skill in the art; and differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

***Relevant Cumulative Documents:***

- a. Barnett et al. US Pat. No. 4,087,555 and 4,129,645 both teach topical (e.g. suspension/emulsion) compositions comprising hectorite clay and a peptizer.
- b. Hughes Kajita: US Pat. No. 5,427,990 and 5,578,219, respectively, provide motivation to "peptize" water soluble clays for use in "water absorbent articles including diapers e.g. improve water absorption.

***Future Correspondences:***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa  
Primary Examiner  
Art Unit 1639

BC  
March 14, 2005

